



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request; Inclusion Enrollment

Report Form Conversion to Common Form, Office of the Director (OD)

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Tawanda Abdelmouti, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 805-C, Bethesda, Maryland 20892, or call a non-toll-free number 301-435-0978 or Email your request, including your address to ProjectClearanceBranch@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register on April 22, 2021, page 21324 (86 FR

21234) and allowed 60 days for public comment. No public comments were received.

The purpose of this notice is to allow an additional 30 days for public comment.

Office of the Director, Office of Extramural Research (OER), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Inclusion Enrollment Form Conversion to Common Form - NEW, 0925-XXXX, Expiration Date XX/XX/XXXX, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: NIH's Office of Extramural Research (OER) Office of Policy and Extramural Research Administration (OPERA) is converting the Inclusion Enrollment Report form to allow its use by the Department of Defense (DoD). The Inclusion Enrollment Report is used for all applications involving NIH-defined clinical research. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 194,574.

Estimated Annualized Burden Hours

Information Collection Forms	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Inclusion enrollment form	64,858	1	3	194,574

Total	-----	64,858	-----	194,574

Dated: July 30, 2021.

Lawrence A. Tabak,

Principal Deputy Director,

National Institutes of Health.

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